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EXAMINER

GARCIA, M

ART UNIT

PAPER NUMBER

1627

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File copy

Office Action Summary

Application No.

09/163,199

Applicant(s)

Fukushima et al

Examiner

Maurie E. Garcia, Ph. D.

Art Unit

1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on May 11, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 3-18, and 20-26 is/are pending in the application.

4a) Of the above, claim(s) 3-6, 9-17, and 20-26 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 7, 8, and 18 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 15

20) ☐ Other: _____

DETAILED ACTION

1. Applicant's Response filed May 11, 2001 (Paper No. 14) is acknowledged. Claim 1 was amended, claims 2 and 19 were cancelled and no claims were added. Therefore, claims 1, 3-18 and 20-26 are pending. Further consideration has necessitated new rejections. Since the new rejections were not entirely necessitated by amendment to the claims, the case is maintained in non-final status.

2. Claims 5, 6, 9-17 and 21-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions, the requirement having been traversed in Paper No. 11. Claims 3, 4 and 20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species. Election was made **without** traverse in Paper No. 11 with respect to the species.

3. Therefore, claims 1, 7, 8 and 18 are examined on the merits in this action.

Withdrawn Rejections

4. Some of the previous rejections under 35 U.S.C. 112, second paragraph have been withdrawn in view of applicant's cancellation of claims and claim amendments. Maintained rejections are set forth below along with response to arguments. The previous rejections under

35 USC 102 have been withdrawn in view of applicant's arguments and amendments. New rejections and objections are also set forth below.

Maintained Rejections
Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "micro-dots" in claim 1 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. That is, what is the size of such "micro-dots"?

Response to Arguments

7. Applicant's arguments filed May 11, 2001 have been fully considered but they are not found persuasive. The examiner's rationale is set forth below.

8. The examiner maintains that the term “micro-dots” in claim 1 is still unclear. Applicant is directed to MPEP 2173.05(a): [t]he meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. The examiner deems that due to the lack of disclosure in the instant specification and the relative nature of the term, one of ordinary skill would not know the metes and bounds of the claim.

9. Applicant argues that one of ordinary skill is reasonably apprised of the meaning of this term and refers to “an ink-drop ejected from an ink-jet nozzle” (Response, page 2, 3rd paragraph) and gives various volume/diameter/density definitions. In response to this argument, it is noted these features (e.g. ink-drops, ink-jet nozzle, volume/diameter/density etc.) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, it is not apparent that any of the volume/diameter/density definitions are even set forth in the instant specification. Note the instant claim 1 recites *only* “printing a solution of thin film material as micro-dots”. No reference as to the method of printing, specific solution printed or any other limitations are recited.

***New Objections
Specification***

10. The instant specification is objected to because of the following informalities: The specification refers to the claims (by claim number) in several instances. See, for example, page

4, lines 22, 25 and 26 & page 5, lines 2, 3 and 14. Appropriate correction is requested as this adds a great deal of confusion to the instant specification.

New Rejections
Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: The claim is drawn to a “method of manufacturing a sensor device comprising a circuit having organic thin films formed on electrodes” where the device is further formed on a plastic substrate and the circuit comprises “poly-silicone thin film transistors”. Organic thin films are “printed” on the electrodes. *No* specific methodologies are set forth for preparing such devices and no other structural limitations are set forth. Such represents very broad scope.

(3 and 5) The state of the prior art and the level of predictability in the art: Methods for manufacturing chemical sensors utilizing thin film transistors were known at the time of filing; however, only limited numbers of these methods were known and the specification gives no guidance to permit one of skill in the art to devise strategies for manufacturing a sensor as instantly claimed. The specifics on the manufacturing steps are sufficiently diverse and one of ordinary skill would not be able to predict such steps. Applicant’s claim represents only an invitation to experiment regarding possible sensor set-ups.

For example, Ackley et al (5,719,033) discloses a chemical sensor including a thin film transistor (see Abstract). An “indicator film” is used as the sensing element which is *particularly* situated in order to provide a response, see columns 1-2 of the patent, especially column 1, line 55 through column 2, line 3.

(4) The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. Such persons of ordinary skill in this art, given its unpredictability,

would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have provided *no* examples of manufacturing the sensors as instantly claimed. One of ordinary skill could not guess, *a priori*, how to carry out the claimed invention with regards to the manufacturing steps for creating “poly-silicone thin film transistors” on a plastic substrate and then “printing” organic films thereon. The instant specification lacks an enabling disclosure as to how to make such sensors as the particulars on the location of the “poly-silicone thin film transistors”, electrodes/microelectrodes and positions of the “printed” organic thin films is not set forth.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: In claim 8 there is only the broad recitation that a sensor device is manufactured comprising a circuit having organic thin films formed on electrodes where the device is further formed on a plastic substrate and the circuit comprises “poly-silicone thin film transistors”. *No* specific methodologies are set forth for the manufacture of such devices. Thus, the instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the claimed invention. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as

broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the claimed invention.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 lacks clear antecedent basis for the term “microelectrodes”. Line 2 of the claim recites “electrodes”; however the claim goes on to recite “printing a solution...onto surfaces of *microelectrodes*” (emphasis added).

B. Also, the limitation in claim 1 of “printing a solution of thin-film material as micro-dots onto surfaces of microelectrodes” is rejected as indefinite. The previous rejection (maintained above) discusses the indefiniteness of the term “micro-dots” per se. Upon further review, the entire phrase is deemed to be indefinite. It is confusing and unclear as to the relationship of the “micro-dots” and the microelectrodes. The claim first recites “organic thin films formed on electrodes”, which appears to imply that the films cover the electrodes. However, the limitation in question refers to printing “micro-dots

onto surfaces of microelectrodes". Do these "micro-dots" completely cover the microelectrodes?

New Rejections
Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

16. Claims 1, 7 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Musho et al (US 5,250,439; of record, see previous action, paragraph 18).

Note: for the purposes of this rejection, the examiner is interpreting the application of a polymer in solution to form a thin film on a microelectrode by Musho et al to read on "printing a solution of thin-film material as micro-dots onto surfaces of microelectrodes", see elaboration below.

Musho et al disclose a conductive sensor and use in diagnostic assay where the sensor is miniaturized and uses a conducting polymer (see Abstract). The sensors "utilize the unique electrical properties of conducting polymers to determine the presence and concentration of a predetermined analyte" (see column 12, lines 9-12) and are based on "the oxidative doping of a conducting polymer" such as a polythiophene (see column 16,

line 58-63, for example). The conductive sensor “allows an accurate and sensitive electrical transduction of an analyte-oxidase interaction” (see column 12, lines 48-50) reading on the transducing element of instant claim 1. Specifically, Figure 2 of the reference discloses microelectrodes having a “gap” filled with conducting polymer. This polymer is applied as a “thin, uniform layer or film” (see column 21, lines 55-61, for example). The conductive polymers used by Musho are especially chosen for their processibility in solution and can be applied by ink-jet printing (see column 22, lines 49-65), reading on the limitations of claims 1 and 18. See especially column 31, lines 53-65 which discusses the manufacture of the sensors using conductive polymers in solution. Using plastic as a base is also disclosed, see column 41, lines 1-2.

17. Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis et al (US 5,571,401).

Note: for the purposes of this rejection, the examiner is interpreting the application of a polymer in solution to form a thin film on a microelectrode by Lewis et al to read on “printing a solution of thin-film material as micro-dots onto surfaces of microelectrodes”, see elaboration below.

Lewis et al disclose chemical sensors for detecting analytes in fluids (see Abstract and Figures 1A-B). These sensors contain nonconductive and conductive materials; the conductors can be organic conductors such as polymers (see column 4, lines 20-27). The materials can both be soluble in a common solvent, see column 5, especially lines 14-54

regarding the conductive polymer poly(pyrrole). The resistance of the film changes upon sorption of an analyte, thus transducing the interaction into an electrical signal (reading on the transducing element of instant claim 1), see column 6, lines 9-28, for example. Fabrication of sensors using poly(pyrrole) is specifically disclosed, see column 8, lines 34-54. Lewis discloses that sensor arrays can be scaled up to IC design technologies and can be produced by ink-jet technology (column 6, lines 47-67), reading on the limitations of claim 18.

Status of Claims/ Conclusion

18. No claims are allowed.
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.
20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of

Application/Control Number: 09/163,199
Art Unit: 1627

Page 12

a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D.
July 24, 2001


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